

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA v4 Reference Material AF5%		
Material Number:	0710-3990	Batch Number:	10775974
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs in plasma-like matrix		
Fill Volume:	5 mL		
Date of Manufacture:	26 AUG 2025	Expiration Date:	26 AUG 2027
Storage:	-20 °C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 25 ng/mL Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 34.5 ng/mL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	214 bp		
Acceptance criteria for average size:	150 – 230 bp		
Digital PCR Method:	Bio-Rad QX200™ Droplet Digital™ PCR System		
Digital PCR release criteria:	4.00 – 6.00% for variant allele frequency (VAF) and 7.00 – 9.10 total copies for copy number variants Note: 95% confidence interval examined if reported estimate does not fall within this range; confidence intervals reported in parentheses in table below.		
NGS Method:	Illumina TruSight™ Oncology 500 ctDNA sequenced on NovaSeqX Plus 10B/25B (150PE)		
NGS release criteria:	The extracted cfDNA is made into a library that is successfully sequenced		

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF5%

SNVs and Indels

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	4.99 (4.66-5.33)	4.01
AR	c.2623C>T	p.H875Y	10.97 (10.28-11.67) ¹	11.64 ¹
ATM	c.1058_1059del	p.C353Sfs*5	4.90 (4.56-5.24)	3.71
BRAF	c.1799T>A	p.V600E	4.56 (4.19-4.96)	4.53
BRCA1	c.1961del	p.K654Sfs*47	4.94 (4.56-5.32)	5.15
BRCA2	c.7934del	p.R2645Nfs*3	5.47 (4.87-5.97)	3.61
CDKN2A	c.9_32dup	p.A4_P11dup	5.84 (5.33-6.36)	NA
CHEK1	c.676del	p.T226Hfs*14	5.15 (4.73-5.57)	NA
CHEK2	c.1029_1030delinsGT	p.K373*	5.43 (5.04-5.81)	3.15
EGFR	c.2369C>T	p.T790M	6.33 (5.78-6.83)	4.86
EGFR	c.2303G>T	p.S768I	5.70 (5.33-6.07)	4.38
EGFR	c.2389T>A	p.C797S	6.33 (5.78-6.83)	4.70
EGFR	c.2573T>G	p.L858R	5.28 (4.93-5.63)	4.91
EGFR	c.2310_2311insGGT	p.D770_N771insG	5.70 (5.33-6.07)	4.12
EGFR	c.2235_2249del	p.E746_A750del	4.91 (4.56-5.26)	5.37
ERBB2	c.2313_2324dup	p.Y772_A775dup	4.82 (4.66-4.98)	4.97
ESR1	c.1613A>G	p.D538G	5.18 (4.83-5.53)	4.97
FGFR3	c.746C>G	p.S249C	4.18 (3.87-4.49)	3.83
HRAS	c.37G>C	p.G13R	5.37 (5.01-5.73)	5.30
HRAS	c.182A>G	p.Q61R	5.37 (5.01-5.73)	5.97
IDH1	c.394C>T	p.R132C	5.22 (4.73-5.72)	2.99
IDH2	c.419G>A	p.R140Q	4.46 (4.15-4.76)	4.04
IDH2	c.515G>A	p.R172K	4.57 (4.27-4.88)	4.85
KIT	c.2361+67_2361+72delTTTTTT	N/A	4.90 (4.59-5.21)	NA
KIT	c.2447A>T	p.D816V	5.42 (5.09-5.75)	4.05
KRAS	c.183A>C	p.Q61H	4.74 (4.28-5.18)	4.78
KRAS	c.34G>T	p.G12C	5.45 (5.13-5.77)	4.23
KRAS	c.35G>A	p.G12D	4.98 (4.60-5.37)	3.53
MAP2K1	c.370C>T	p.P124S	5.14 (4.80-5.47)	3.86
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	4.73 (4.42-5.04)	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	4.93 (4.42-5.42)	NA
MET	c.3082+1del	N/A	5.04 (4.82-5.25)	5.46
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	6.17 (5.82-6.52)	2.85
MSH2	c.1662-12_1677del	N/A	5.34 (5.02-5.67)	1.67
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	5.53 (5.19-5.87)	NA

¹The AR variant is present on the X chromosome and the genomic background of this product is male, thus VAF will be ~2-fold higher than other variants.

NA = not assayed; not covered by NGS test panel

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF5%

SNVs and Indels, continued

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	5.11 (4.78-5.44)	3.84
MTOR	c.6644C>A	p.S2215Y	5.19 (4.76-5.62)	4.48
NF1	c.3738_3747del	p.F1247Gfs*16	5.19 (4.71-5.68)	2.22
NRAS	c.182A>G	p.Q61R	5.66 (5.33-6.00)	5.97
NTRK1	c.1783G>A	p.G595R	5.40 (4.90-5.90)	4.31
NTRK2	c.1915G>A	p.G639R	5.91 (5.56-6.25)	5.37
NTRK3	c.1867G>A	p.G623R	5.25 (4.92-5.58)	5.21
PALB2	c.839del	p.N280Tfs*8	5.34 (4.95-5.73)	4.59
PDGFRA	c.2525A>T	p.D842V	4.56 (4.15-4.90)	4.32
PIK3CA	c.3140A>G	p.H1047R	4.91 (3.92-5.78)	4.12
PIK3CA	c.3203dup	p.N1068Kfs*5	4.91 (3.92-5.78)	4.64
PIK3CA	c.1633G>A	p.E545K	4.54 (4.16-4.91)	5.01
PIK3R1	c.1727_1729del	p.T576del	5.30 (4.61-5.92)	2.89
PMS2	c.861_864del	p.R287Sfs*19	4.95 (4.29-5.53)	2.21
PTCH1	c.2307_2308delinsTT	p.R770*	5.36 (4.92-5.71)	3.90
PTEN	c.800del	p.K267Rfs*9	4.22 (3.76-4.68)	3.59
PTEN	c.741dup	p.P248Tfs*5	4.22 (3.76-4.68)	4.01
RAD51C	c.338dup	p.G114Wfs*25	5.20 (4.63-5.71)	1.93
RAD51C	c.242C>A	p.S81*	5.20 (4.63-5.71)	1.74
RAD51D	c.392dup	p.N131Kfs*23	5.01 (4.67-5.35)	3.91
RAD51D	c.271A>T	p.K91*	5.01 (4.67-5.35)	2.95
RAF1	c.770C>T	p.S257L	4.48 (4.11-4.85)	4.21
RB1	c.751C>T	p.R251*	4.33 (3.97-4.69)	2.80
RET	c.2753T>C	p.M918T	4.01 (3.66-4.36)	3.52
SLC7A8	c.-231_-224delTTTTTTTT	N/A	5.15 (4.79-5.51)	NA
SMARCB1	c.118C>T	p.R40*	3.86 (3.23-4.50)	3.26
STK11	c.734+1G>T	N/A	5.06 (4.71-5.42)	2.92
TERT	c.-124C>T	N/A	5.02 (4.63-5.45)	5.54
TERT	c.-146C>T	N/A	5.02 (4.63-5.45)	5.72
TP53	c.723del	p.C242Afs*5	4.67 (4.38-4.97)	3.97
TP53	c.743G>A	p.R248Q	4.67 (4.38-4.97)	4.07
TP53	c.818G>A	p.R273H	4.67 (4.38-4.97)	4.27
TSC1	c.1263+1G>T	N/A	5.07 (4.61-5.45)	3.62
TSC2	c.2640-1G>A	N/A	5.95 (5.58-6.33)	4.32
VHL	c.481C>T	p.R161*	4.00 (3.58-4.42)	4.15
ZNF2	c.*1525_*1530delTTTTTT	N/A	5.54 (4.83-6.15)	NA

NA = not assayed; not covered by NGS test panel

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF5%

Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	5.02 (4.44-5.73)	†
CD74::ROS1	Intron 6::Intron 34	5.46 (5.02-5.90)	†
COL1A1::PDGFB	Intron 25::Intron 1	5.50 (5.11-5.91)	NA
EML4::ALK	Intron 13::Intron 19	5.15 (4.74-5.55)	†
ETV6::NTRK3	Intron 5::Intron 14	5.47 (5.06-5.87)	NA
FGFR2::BICC1	Intron 17::Intron 2	5.64 (4.95-6.27)	†
FGFR3::TACC3	Exon 18::Intron 7	5.87 (5.49-6.25)	†
NCOA4::RET	Intron 7::Intron 11	4.89 (4.54-5.24)	†
PML::NTRK2	Intron 2::Intron 12	5.49 (5.13-5.85)	NA
TPM3::NTRK1	Intron 7::Intron 9	5.92 (5.32-6.39)	NA

NA = not assayed

† ≥ 24 supporting reads detected

Copy Number Variants

Gene	dPCR Total Copies	NGS AF Total Copies
AKT2	6.84 (7.01-6.67)	6.00
CCND1	8.91 (9.13-8.70)	6.59
CCNE1	7.27 (7.44-7.09)	7.26
CDK4	8.77 (8.98-8.57)	7.95
ERBB2	8.39 (8.59-8.19)	7.39
FGF19	8.91 (9.13-8.70)	6.91
FGF3	7.78 (8.04-7.53)	5.96
FGF4	7.78 (8.04-7.53)	5.15
FGFR1	7.69 (7.87-7.51)	6.25
MET	8.33 (8.52-8.13)	11.63
MYC	7.95 (8.14-7.76)	7.10
MYCN	8.52 (9.01-8.02)	9.04

Approval:

Sandita Samidam

10 SEP 2025

Prepared By

Date